EXHIBIT 2

JONES DAY

51 LOUISIANA AVENUE, N.W. • WASHINGTON, D.C. 20001-2113
TELEPHONE: 202-879-3939 • FACSIMILE: 202-626-1700

Direct Number: (202) 879-4645
jmcevoy@jonesday.com

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VIA FACSIMILE

The Honorable Harold Baer, Jr.
United States District Court for the Southern District of New York
500 Pearl Street, Room 2230
New York, New York 10007

Re: *Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis, et al.* (No. 07-CV-7343)
Health Insurance Plan of New York v. Aventis Pharmaceuticals Inc. (No. 07-CV-6785)

Dear Judge Baer:

Defendants Aventis Pharmaceuticals Inc. and sanofi-aventis us llc (collectively, "Aventis") respectfully submit this letter to the Court in advance of the pretrial conference scheduled for Thursday, October 4.[1] Although counsel for plaintiff Louisiana Wholesale (the "Direct Purchasers"), plaintiff Health Insurance Plan of New York (the "Indirect Purchasers"), and Aventis are largely in agreement regarding a general timetable for discovery in the above-captioned litigation, the parties have been unable to agree on the appropriate trigger date for that timetable.

This case presents the novel question whether and under what circumstances Aventis, which manufactures and sells Arava® (a rheumatoid arthritis medication known generically as leflunomide), may be stripped of its *Noerr-Pennington* antitrust immunity for bringing a safety and efficacy concern about generic versions of the drug to the attention of the Food and Drug Administration (the "FDA").[2] Plaintiffs appear to believe that conclusory assertions about the

[1] Sanofi-aventis, a company organized under the laws of and doing business in France, is also named as a defendant in the Direct Purchasers' complaint. Because the conduct that is the subject of the complaint does not involve any employees of sanofi-aventis (and in light of the fact that the Direct Purchaser plaintiffs have not attempted to serve sanofi-aventis under the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters, Nov. 15, 1965, 20 U.S.T. 361, T.I.A.S. No. 6638, 658 U.N.T.S. 163), counsel for the parties have been engaged in negotiations concerning the voluntary dismissal of sanofi-aventis in exchange for a tolling agreement with respect to any claims that might be asserted against it. Those negotiations have not yet reached a conclusion.

[2] The *Noerr-Pennington* doctrine was developed in a trilogy of Supreme Court cases addressing the antitrust immunity provided to a party petitioning the government for protection or redress. *See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 138 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 669-71 (1965); *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11 (1972). A party is entitled to antitrust immunity for petitioning conduct absent sufficient factual allegations that its petitioning activity was objectively baseless (a threshold inquiry) and subjectively baseless (a secondary inquiry). *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993) (setting forth a two part test for "sham

objective merit of a petition and speculative allegations about when and why a party filed it may strip the petitioning party of its antitrust immunity, and leave it vulnerable to claims that its conduct delayed generic manufacturers from coming to market. Plaintiffs are patently wrong. Neither their view of the law nor their characterization of the documents underlying their complaints (collectively, the "Complaints") supports the cause of action they seek to bring, or the Direct Purchasers' rush to conduct discovery concerning classic First Amendment activity.

In light of the paucity of factual support for Plaintiffs' conclusory allegations and the Supreme Court's recent decision in *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955 (2007), Aventis believes that discovery should be limited in scope while the Court weighs motions to dismiss that Aventis will file in the next several weeks.[3] **The Indirect Purchasers agree with Aventis that discovery should not proceed until the Court has ruled on the motions to dismiss. In contrast, the Direct Purchasers have refused to consider any proposal that does not rush headlong into costly and burdensome discovery.**[4] Before turning to the competing proposals a brief overview of the generic drug approval process, the citizen petition, and the Plaintiffs' claims is in order.

The Generic Drug Approval and Citizen Petition Processes

Under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399, (the "FDCA"), pioneer drug manufacturers must file a comprehensive New Drug Application ("NDA") and submit specific data concerning the safety and efficacy of a proposed new drug. In exchange for the substantial amount of work required to prepare an NDA – including, among other things, clinical trials – the FDCA rewards pioneer drug manufacturers with differing periods of marketing exclusivity, the length of which depend on the existence of patent and other protections for particular drugs. 21 U.S.C. §§ 355, 355a.

(continued...)

litigation," which requires a court to first determine that the challenged activity was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" and only then proceed to a determination of the subjective intent of the party).

[3] Among other things, Defendants will challenge the adequacy of the "sham" and relevant market allegations in the Complaints. Defendants will also challenge the antitrust standing of these purchaser plaintiffs to bring a claim based on an alleged injury to generic drug manufacturers. For purposes of this letter – and for illustrating the imprudence of proceeding to extensive discovery – Aventis will focus only on Plaintiffs' fundamental failure to allege facts demonstrating the objective baselessness of the citizen petition.

[4] Specifically, Defendants have proposed to limit discovery to the exchange of transactional data necessary for class certification purposes and to discovery from the FDA, which will likely take longer than a year under any circumstances. *See* http://www.fda.gov/foi/annual2006.html.

The Hatch-Waxman Act, 21 U.S.C. § 355 (the "Act"), created a streamlined process for reviewing and approving generic drugs upon expiration of the NDA holder's exclusivity rights. Specifically, the Act created a pathway by which generic drug manufacturers could file an abbreviated New Drug Application ("ANDA"), rely on the safety and effectiveness data submitted in the original NDA, show that its drug was bioequivalent to the innovator drug, and (with limited exceptions) copy the branded drug manufacturer's labeling information. 21 U.S.C. § 355(j)(2)(A).[5] The Act did not, however, make the FDA's ANDA review and approval process transparent. In fact, *the very existence and substance of an ANDA is confidential*, see 21 C.F.R. § 314.430(b) and (d), and unless a NDA holder possesses certain patent rights entitling it to notice of the ANDA under the Act, the pioneer drug manufacturer may not know that an ANDA has been filed unless and until it has been approved.

In contrast, the FDA's review and consideration of so-called "citizen petitions" is far more transparent. Any person or entity may file a petition asking the FDA to take (or to refrain from taking) a particular action, *see* 21 C.F.R. §103, and the docket for any such petitions is open for the world to see, http://www.fda.gov/ohrms/dockets/default.htm (last visited Oct. 1, 2007).

The Plaintiffs' Allegations With Regard to Aventis and Generic Leflunomide

According to Plaintiffs, branded drug manufacturers have misused the citizen petition process in recent years by filing "sham" petitions intending only to delay generic drug competition. *See, e.g.,* Direct Purchaser Complaint ("DPC") ¶ 38-43; Indirect Purchaser Complaint ("IPC") ¶ 49-53. Attempting to paint Aventis guilty by association, Plaintiffs allege that Aventis abused the citizen petition process to illegally extend the five and a half year marketing exclusivity provided to it as the NDA holder for Arava®, DPC ¶¶ 46; 55-58; IPC ¶¶ 56, 70, and to limit competition for the 10mg and 20mg dosages for which generic manufacturers submitted ANDA applications to the FDA, DPC ¶ 51, IPC ¶ 60.

Plaintiffs acknowledge that the FDA-approved label for Arava® includes a reference to an initial loading dose of one 100 mg tablet for three days. DPC ¶ 45; IPC ¶ 55. They also admit that the citizen petition sought to require the generic manufacturers to include a 100mg loading dose in their labels (as the FDA had required Aventis to do), or to prove that five of their 20mg tablets were bioequivalent to one 100mg tablet (as the FDA had required Aventis to show in connection with the NDA on which the ANDAs relied). DPC ¶ 55; IPC ¶ 65.

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[5] For example, labeling changes attributable to fact that "the new drug and the listed drugs are produced by different manufacturers" may be permissible under certain circumstances. 21 U.S.C. § 355(j)(2)(A)(v).

Plaintiffs' Selective and Conclusory Allegations About the Leflunomide Citizen Petition Cannot State a Sherman Act Section 2 Claim[6]

Plaintiffs engaged in a highly selective cherry-picking exercise when deciding what to include in the Complaints. While Plaintiffs were quick to capitalize on facts that could be painted for their benefit, they chose to gloss over or omit three critical facts that dispose of their assertion that the petition was objectively baseless.

First, Plaintiffs' allegations are premised on the erroneous assertion that Aventis knew or should have known what the ANDAs contained, and that Aventis made certain statements notwithstanding its knowledge of facts to the contrary. DPC ¶ 57; IPC ¶ 67. But the FDA keeps the very existence and substance of ANDAs confidential, *see* 21 C.F.R. § 314.430(b) and (d), and Plaintiffs have admitted that Aventis was not entitled to any notice of the ANDAs under the Act. DPC ¶ 46; IPC ¶ 4. Under the circumstances, a reasonable litigant would certainly expect the FDA to hold generic manufacturers to the same standards imposed on the NDA holder, either by requiring reference to a 100mg loading dose or by demonstrating the bioequivalence of five 20mg tablets to a 100mg tablet.

Second, although the FDA denied the citizen petition, it did so only *after* a seven-page explanation of its decision and a critical note that *"in light of the discussion above,* FDA *will require* the labeling for generic leflunomide products to include the labeling approved for [Arava®] concerning the use of a 100-mg loading dose." DPC, Exh. 1, at 7; IPC, Exh. B at 7 (emphasis added). In *PRE,* the Supreme Court cautioned that a court "must resist the understandable temptation to engage in post hoc reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." *Id.,* 508 U.S. at 60 n. 5. Here, the fact that the FDA denied the petition but still took some action in response to it makes the need for caution even stronger.

Third, the letters approving the generic manufacturers' ANDAs (upon which Plaintiffs must have relied to ascertain the approval dates identified in the Complaints, *see* DPC ¶ 62; IPC ¶ 71) reflect the fact that those companies filed no fewer than *seventeen* amendments to their ANDAs *after* Aventis filed the citizen petition. That the FDA did so reveals that the citizen petition had merit and required responses by the generic manufacturers, *and/or* the ANDAs were fundamentally deficient and could not be approved without repair. Under either scenario, the law would not attribute an antitrust injury to Aventis' petitioning conduct.

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[6] A Section 2 claim requires Plaintiffs to allege facts sufficient to show (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power. *Volvo North Am. Corp. v. Men's Intern. Prof'l Tennis Council*, 857 F.2d 55, 73 (2d Cir. 1988). Furthermore, an antitrust complaint must adequately define the market, allege conduct in violation of the antitrust laws and allege an antitrust injury. *Global Discount Travel Servs., LLC v. Trans World Airlines, Inc.*, 960 F. Supp. 701, 704 (S.D.N.Y. 1997) (*quoting Re-Alco Indus., Inc. v. Nat'l Ctr. For Health Educ., Inc.*, 812 F. Supp. 387, 391 (S.D.N.Y. 1993)).

There is no doubt that Plaintiffs reviewed the FDA docket when preparing their Complaints, as they were required to do by Fed. R. Civ. P. 11 and as evidenced by the fact that they have attached the citizen petition and the FDA's response to it as exhibits to the Complaints.[7] Given the entire citizen petition file, it is simply not reasonable for Plaintiffs to assert – as they have in entirely conclusory fashion – that the petition was without foundation.[8]

In short, Plaintiffs' selective recitation of facts drawn from documents attached to the Complaints does not satisfy Plaintiffs' burden of alleging facts sufficient to show that Aventis' petition was objectively baseless. The Court can and should take account of the entire citizen petition file when considering Aventis' motions to dismiss, and doing so will not convert the Rule 12 motions into Rule 56 motions requiring discovery. *ATSI Communications, Inc. v Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (citing *Rothman v. Gregor*, 220 F.3d 81, 88 (2d Cir. 2000)) (finding that on a motion to dismiss, the court may consider "any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference . . . and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit."); *accord Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 n.4 (2d Cir. 2002) (affirming district court's consideration of plaintiffs' recording contracts, which were not attached to the complaint, because "the Amended Complaint is replete with references to the contracts and requests judicial interpretation of their terms").[9]

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[7] The copies attached to the Complaints did not include the exhibits Aventis provided to the FDA, or the responses of two generic companies to the petition. Aventis will gladly provide the Court with a courtesy copy of the entire citizen petition file at the status conference tomorrow.

[8] Nor is it reasonable for Plaintiffs to allege that the relevant market should be limited to leflunomide. Exhibits to the citizen petition identify hydroxychlorioquine, sulphasalzaine, methotrexate, IM gold, penicillamine, auranofin, azathioprine, and cyclosporine as other disease-modifying rheumatoid arthritis medications, refuting Plaintiffs' self-serving and wholly conclusory allegations that Aventis possessed monopoly power in a relevant market. *See* DPC ¶ 74 ; IPC ¶ 24. A plaintiff's failure to "define its market by reference to the rule of reasonable interchangeability [of products] is, standing alone, valid grounds for dismissal." *Tower Air, Inc. v. Fed. Express Corp.*, 956 F. Supp. 270, 280 (E.D.N.Y. 1996); *see also Re-Alco Indus., Inc. v. Nat'l Ctr. for Health Ed., Inc.* 812 F. Supp. 387, 391 (S.D.N.Y. 1993) ("If a complaint fails to allege facts regarding substitute products, to distinguish among apparently comparable products, or to allege other pertinent facts relating to cross-elasticity of demand . . . a court may grant a Rule 12(b)(6) motion.").

[9] In this case, and with the benefit of the entire citizen petition file before it, the Court may decide the question of objective baselessness on a motion to dismiss since there can be no dispute about the predicate facts of the petition. As the Court observed in *New York Jets LLC v. Cablevision Sys. Corp.*, 2005 U.S. Dist. LEXIS 33362 at *6-7 (S.D.N.Y. Dec. 14, 2005):

> A court can (*and should*) determine whether a litigant lacked 'probable cause' [to bring suit] as a matter of law . . . [when] there is no dispute over the predicate facts of the underlying legal proceeding. However, where, [as in the *Jets* case] such facts *are* in dispute, there is no requirement that a court determine whether the 'sham' exception applies without the benefit of full discovery.

Id. (emphasis added and internal citation omitted).

Indeed, the readily-apparent defects in Plaintiffs' claims – as well as the additional legal arguments that Aventis will put forth in its motions to dismiss the Complaints – strongly suggest that the Court should defer active discovery until the motions have been resolved.[10] As the Supreme Court stated in *Twombly,* "something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with 'a largely groundless claim' be allowed to 'take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value.'" *Twombly*, 127 S.Ct. at 1966 (internal citations omitted). Thus, the Court continued, "when the allegations in a complaint, however true, could not raise a claim of entitlement to relief, 'this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.'" *Id.* (citing 5 Wright & Miller § 1216, at 233-234).

In this case, the very documents on which Plaintiffs have relied to construct their complaint dispose of the conclusory allegation that the citizen petition was objectively baseless. In the absence of facts to support that assertion, Aventis cannot be stripped of its antitrust immunity, and it certainly should not be subject to costly discovery that will lead to the same and inevitable conclusion. *See, e.g., Car Carriers, Inc.* v. *Ford Motor Co.*, 745 F.2d 1101, 1106 (7th Cir. 1984) ("The costs of modern federal antitrust litigation and the increasing caseload of the federal courts counsel against sending the parties into discovery when there is no reasonable likelihood that the plaintiffs can construct a claim from the events related in the complaint"). Accordingly, Aventis respectfully requests that the Court enter the proposed scheduling orders (attached as Exhibits A and B) which provide for a twelve month pretrial schedule (to the extent one is necessary at all) triggered by the resolution of Aventis' motions to dismiss the Complaints.[11]

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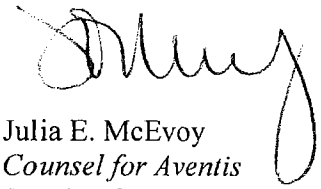
[10] Notably, the cases on which Direct Purchasers rely for the erroneous proposition that Aventis cannot justify a stay of discovery are wholly inapplicable to the facts of this case. *See Hachette Distribution, Inc. v. Hudson County New Co., Inc.*, 136 F.R.D. 356 (E.D.N.Y. 1991) (noting that the motion to dismiss would not have resulted in the complete termination of the action and some discovery had already occurred); *ADL, LLC v. Tirakian*, 2007 U.S. Dist. LEXIS 48640 (E.D.N.Y. July 5, 2007) (denying stay because discovery was inevitable in a case where some but not all of the defendants filed dispositive motions); *Association Fe Y Allegria v. Republic of Ecuador*, 1999 U.S. Dist. LEXIS 4815 (S.D.N.Y. March 16, 1999) (finding that a stay would prejudice the plaintiffs).

[11] Aventis has negotiated one schedule with the Direct Purchasers (attached as Exhibit A), as to which the trigger date and a handful of minor differences remain in dispute. Aventis has negotiated a separate schedule with the Indirect Purchasers (attached as Exhibit B), which is triggered by the resolution of the motions to dismiss. It also differs from the schedule Aventis negotiated with the Direct Purchasers as it provides for a slightly longer briefing schedule for the motion to dismiss, since the Indirect Purchasers intend to amend their complaint next week. It also provides additional flexibility about the timing of any dispositive motions, since the Indirect Purchasers believe that their case may be more manageable as a result of the impending amendment. The only disagreement between Aventis and the Indirect Purchasers relates to the possibility of some bifurcation between liability and damages discovery.

I look forward to the opportunity to discuss this further with the Court tomorrow.

Very truly yours,



Julia E. McEvoy
Counsel for Aventis
(Motion for admission *pro hac vice* pending)

EXHIBIT A

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

LOUISIANA WHOLESALE DRUG CO., INC., Plaintiff, v. SANOFI-AVENTIS, SANOFI-AVENTIS U.S., LLC and AVENTIS PHARMACEUTICALS, INC., Defendants.	Civil Action No. 07-cv-7343 (HB) Hon. Harold Baer, U.S.D.J.

PROPOSED PRETRIAL ORDER NO. 1

WHEREAS, Plaintiffs have filed a complaint in the above-captioned action (the "Direct Purchaser Action") for alleged violations of federal and/or state antitrust laws involving the drug Arava® ("Arava") and its generic equivalents; and

WHEREAS, the following schedule will avoid unnecessary costs and promote the efficient conduct of proceedings herein;

NOW, THEREFORE, THE COURT ORDERS as follows:

1. Rule 12 Briefing Schedule: The following briefing schedule applies to an answer or any other response to be filed under Rule 12 against the complaints in the Direct Purchaser Action:

(a) Answer or opening briefs filed: October 15, 2007

(b) Any briefs in response filed: November 15, 2007

(c) Any reply briefs filed: December 7, 2007

2. Discovery and Pretrial Schedule: The following schedule shall apply to all discovery and pretrial proceedings in the Direct Purchaser Action. The timing of all events set

forth in the schedule below shall be calculated in relation to the date of entry of an order by this Court on the Rule 12 motions discussed in Paragraph 1 above, provided such order allows Plaintiffs' claims to proceed (the "Decision Date"):

(a)	Written discovery requests due	Immediately on Decision Date
(b)	Agreed-upon protective order	Decision Date + 15 days
(c)	Rule 26(a) disclosures	Decision Date + 30 days
(d)	Written responses to discovery requests	Decision Date + 30 days
(e)	Deadline for addition of claims/ parties/defenses	Decision Date + 90 days
(f)	Plaintiffs' motion for class certification	Decision Date + 90 days
(g)	Defendants' opposition to motion for class certification	Decision Date + 135 days
(h)	Plaintiffs' reply to motion for class certification	Decision Date + 180 days
(i)	Close of fact discovery	Decision Date + 180 days
(j)	Expert reports due	Decision Date + 210 days
(k)	Rebuttal reports due	Decision Date + 240 days
(l)	Reply reports due	Decision Date + 255 days
(m)	Dispositive motions due	Decision Date + 270 days
(n)	Oppositions to dispositive motions due	Decision Date + 290 days
(o)	Replies to dispositive motions due	Decision Date + 300 days
(p)	Joint pretrial order due	Decision Date + 355 days
(q)	Trial	Decision Date + 365 days

The Court, pursuant to the parties' agreement, will allot 12 days for trial in the Direct Purchaser Action.

SO ORDERED:

DATED: _____
New York, NY

_____
UNITED STATES DISTRICT JUDGE

EXHIBIT B

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

HEALTH INSURANCE PLAN OF NEW YORK, INC., Plaintiff, v. AVENTIS PHARMACEUTICALS, INC., Defendant.	Civil Action No. 07-cv-6785 (HB) Hon. Harold Baer, U.S.D.J.

PROPOSED PRETRIAL ORDER NO. 1

WHEREAS, Plaintiffs have filed a complaint in the above-captioned action (the "Indirect Purchaser Action") for alleged violations of federal and/or state antitrust laws involving the drug Arava® ("Arava") and its generic equivalents; and

WHEREAS, the following schedule will avoid unnecessary costs and promote the efficient conduct of proceedings herein;

NOW, THEREFORE, THE COURT ORDERS as follows:

1. Amended Complaint: Plaintiffs shall file an amended complaint on or before October 12, 2007.

2. Rule 12 Briefing Schedule: The following briefing schedule applies to an answer or any other response to be filed under Rule 12 against the complaints in the Indirect Purchaser Action:

(a)	Answer or opening briefs filed:	November 2, 2007
(b)	Any briefs in response filed:	November 30, 2007
(c)	Any reply briefs filed:	December 14, 2007

2. Discovery and Pretrial Schedule: The following schedule shall apply to all discovery and pretrial proceedings in the Indirect Purchaser Action. The timing of all events set forth in the schedule below shall be calculated in relation to the date of entry of an order by this Court on the Rule 12 motions discussed in Paragraph 2 above, provided such order allows Plaintiffs' claims to proceed (the "Decision Date"):

(a)	Written discovery requests due	Immediately on Decision Date
(b)	Agreed-upon protective order	Decision Date + 15 days
(c)	Rule 26(a) disclosures	Decision Date + 30 days
(d)	Written responses to discovery requests	Decision Date + 30 days
(e)	Deadline for addition of claims/ parties/defenses	Decision Date + 90 days
(f)	Plaintiffs' motion for class certification	Decision Date + 90 days
(g)	Defendants' opposition to motion for class certification	Decision Date + 135 days
(h)	Plaintiffs' reply to motion for class certification	Decision Date + 180 days
(i)	Close of fact discovery	Decision Date + 180 days
(j)	Expert reports due	Decision Date + 210 days
(k)	Rebuttal reports due	Decision Date + 240 days
(l)	Reply reports due	Decision Date + 255 days
(m)	Dispositive motions due	Decision Date + 270 days[1]
(n)	Oppositions to dispositive motions due	Decision Date + 290 days
(o)	Replies to dispositive motions due	Decision Date + 300 days

[1] The parties have agreed that they may file dispositive motions *no later than* the Decision Date + 270 days. Should a party wish to file a dispositive motion any earlier than that date, the same response intervals as set forth above for dispositive motions will determine the briefing schedule.

(p)	Joint pretrial order due	Decision Date + 355 days
(q)	Trial	Decision Date + 365 days

The Court, pursuant to the parties' agreement, will allot 12 days for trial in the Indirect Purchaser Action.

SO ORDERED:

DATED:_____
New York, NY

_____
UNITED STATES DISTRICT JUDGE